and Parker. The Roman Catholic Church's contributions to public policy are based not only on their moral or ethical principles, but on an effectively arbitrary and dogmatic application of those principles that is backed by the full force of what is effectively a very powerful lobby group in many countries.

Like Skene and Parker, I have no answer to the problems I have raised. Historically one thing is certain, in the future the Roman Catholic Church's current position on the embryo will be judged to have been right or wrong with the wisdom of hindsight. Just as we judge the Church's persecution of Galileo almost 400 years ago now.

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Non-compliance: a side effect of drug information leaflets

The problem of non-compliance with treatment and its repercussions on the clinical evolution of different conditions has been widely investigated.[1–4] Non-compliance has also been shown to have significant economic implications, not only as a result of product loss but also indirectly through the complication of disease management and its subsequent healthcare and social costs.[5–7]

Non-compliance as a health problem

The term ''non-compliance'' might be taken to refer both to the failure to follow a drug regimen and to the failure to adopt other measures that contribute to improvement in health—for example, changes in lifestyle or diet. This letter focuses on the former.

Non-compliance with a drug regimen can be the result of a number of different factors[9–11] and a variety of techniques have been developed in an attempt to control it.[12 13] Of these, the few techniques that have been shown to be effective have only managed to solve the problem in specific situations over short periods of time. The use of such techniques to control non-compliance, particularly where these are effective, raises interesting ethical questions about the extent to which their application constitutes an infringement of the patient's right to decide on how to manage their own health.[8] Here we suggest that in some cases one factor that leads to non-compliance is the tendency to provide extensive and exhaustive information on side effects in patient information leaflets. Consider the following case.

A true story

One morning Dr Smith woke up with a slight cold—muscular aches, headache, chills, and nasal congestion. He decided to take some medicine to counteract its effects. His initial thought was to find something to combat his runny nose, so he chose a product specially indicated for nasal congestion: ''StopSnot''. After reading the product information leaflet, however, Dr Smith felt another kind of chill run down his spine. He was struck cold by the contraindications, warnings, interactions, precautions, and adverse reactions listed in the leaflet. If he used this drug, it said, he would run the risk of suffering nausea, anxiety, agitation, insomnia, hallucinations, convulsions, amazement, weariness, arrhythmia, dizziness … . Rather than risk all of this, he thought, why not suffer a few bothersome snuffles? For his muscular aches, Dr Smith chose another drug, ''Abatache'', but the risks described in the accompanying information leaflet seemed even worse. These included baldness, skin blistering, aseptic meningitis, pneumonitis, fatal hepatitis, gastrointestinal perforation, blood in the urine, jaundice, kidney disease, peptic ulceration, mouth ulceration, visual abnormality … . So in the end, armed with his clinical and pharmacological knowledge, Dr Smith simply opted to continue blowing his nose and suffer a few muscular aches. He had no desire to play Russian roulette with his health.

The principle of autonomy and the right to information

The principle of autonomy in medical ethics places the patient at the centre of medical decision making about his or her care. It places particular emphasis on the importance of informed consent, and suggests that, except in rare situations,[14] no patient should undergo medical treatment or surgical intervention without his or her fully informed authorisation. This is the basis of patient-centred medicine.

To obtain valid informed consent, it is argued that the patient must receive sufficient understandable information to make a fully informed choice. In practice this means that someone undergoing a specific treatment receives information from at least two sources. First they will be given direct information from their doctor or another health professional about the drug to be taken, recommended lifestyle changes, and perhaps a warning of the hazards related to non-compliance. At this time, they will also be provided with information on some of the side effects attributed to the drug being prescribed. Individual patients will tend to understand this information in a range of different ways, and it is well recognised that they will respond with a variety of known behaviour patterns.[8]

Secondly, the patient will also receive additional information on side effects from the information leaflet provided with the drug itself. These leaflets tend to cite each and every one of the undesirable effects related—note ''related''—to the principle active ingredient used in the drug. The information can in some cases be so complete or detailed that even any extremely unusual syndrome described in relation to the use of the drug will inevitably be listed in the leaflet as a possible ''side effect''.

This information can sometimes have a significant effect on the likelihood that a patient will take the drug in question and may lead to significant ''non-compliance''. When patients with minor ailments read about all the problems that may occur from using the prescribed medication, they may start worrying, to say the least. Some people read the leaflet again and again. They may then consult another source of medical information such as a website and perhaps decide to take only half the dose for half the amount of time prescribed, or simply decide not to take the medicine at all.

In addition to the problem of non-compliance, the so called nocebo effect[15] needs to be considered, whereby the patient's mindset is often a key element in the appearance of either physical or imaginary side effects, as has been shown in various studies.[16 17] Such an effect may be caused by information leaflets.

Complete information versus sufficient information

Practically any city dweller would refuse to use transport services, work tools, or recreational facilities if they were supplied with complete, absolute, and extensive information on the hazards using these might entail. Precautions and warnings are usually good things, but they should be kept within reasonable limits to avoid creating outright alarm. Too much information can sometimes undermine autonomy and also lead to significant harms through non-compliance.

It was shown some years ago[18] that information supplied by doctors can generate side effects that cannot subsequently be corroborated by physical examination. As it happens all too often, the information was not as exhaustive or complete as it might be.

In view of this, we believe that the kind of information given in drug descriptions should be reassessed. The information should be true, accurate, and easy to understand in as complete a way as possible, but it should not generate alarm that can lead to deleterious consequences in the healthcare sector or in the economic sphere.

So what did the patient decide?

The patient, shocked and dismayed at the drug's side effects, finally decides not to follow the doctor's recommendation. He (or she) will try to relax, perhaps by smoking a cigarette laced with nicotine, tar, and a number of other substances. True enough, doctors recommend giving up smoking. But who will listen to what a doctor says about smoking when they appear to be prescribing drugs truly hazardous to health? After all, a pack of cigarettes only says that cigarette smoking seriously damages your health. There is certainly no leaflet listing each and every one of its possible side effects. Tobacco kills, but it sometimes looks as if medication is worse.

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Symposium on consent and confidentiality. *J Med Ethics* 2003;29:2–40

We read with interest the papers on informed consent published in a recent issue of the *Journal of Medical Ethics*.[1] Whatever their differences, and however much they questioned some aspects of the duty to respect autonomy through attempting to obtain informed consent for therapeutic interventions, there was general agreement that competent adult patients are entitled to a core of basic information about their treatment options. There was also consensus that training in the process of obtaining consent is important. In our experience, two dimensions of such training are of particular interest. On the one hand, students require good theoretical understanding of the ethical and legal background to the professional emphasis now placed on informed consent. On the other hand, they need practical training in the relevant communication skills and how to apply them to obtain consent for specific clinical procedures. To do so, doctors must obviously also have a good understanding of these procedures. We recently encountered serious problems as regards such understanding in a study among junior doctors in England (Schildmann J, Cushing A, Doyal L, Vollmann J. The ethics and law of informed consent: knowledge, views and practice of pre registration house officers, submitted for publication). No matter how good their philosophical and legal knowledge, preregistration house officers (PRHOs) will not be able to deliver the minimal standards of informed consent outlined by O'Neill unless, suffice it to say, they know what—practically speaking—they are talking about.[2]

In contrast to Bravo *et al*'s results (in the same issue of the journal), almost all the PRHOs who took part in our survey had good legal understanding of the differences between competent and incompetent patients.[3] This may be interpreted as a positive result of the change in the curriculum at their particular medical school, which includes extensive sessions about informed consent. These embrace ethics, law, and communication skills. However, despite their understanding, the junior doctors in our study still experienced problems about their role in the consent process. The problems pertained to pressure of time and lack of support by senior doctors, as well as pressure on them at times to obtain consent in circumstances where they had been taught that they should not. This gap between the standards of informed consent currently taught to medical students and the clinical realities they face, and into which they are thrust, is an ongoing problem.[4]

If informed consent is to fulfil the purpose of respecting the autonomy and dignity of patients, sufficient resources are required to train young doctors to do the job properly, especially as regards their understanding of procedures for which they are providing information and their competence as communicators. One thing is clear: if they cannot complete the task in accordance with the guidance issued by both the General Medical Council and the Department of Health, they should not be doing it at all.[5 6] Trusts and colleges should ensure that all supervisory staff are aware of their responsibilities in this regard.

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Response to ''Patient organisations should also establish databanks on medical complications''

Gebhardt in his brief report[1] pleads for patient organisations to establish databanks on medical complications. Given the references (for example, an article by Paans, a journalist, entitled ''Medical errors to be kept secret'') and the lack of argumentation, there is substantial danger of misinterpretation of the current situation, which in turn may frustrate the process of increased transparency. We would therefore like to respond to this by giving background information and reasons for some of the choices that were made with respect to the registry of complications mentioned by Gebhardt.

First, a distinction needs to be made between an error and an adverse outcome, which are often confused. From Gebhardt's reference to the journalist's article which discusses the same registry of adverse outcomes, but with the title referring to errors, both Gebhardt and the journalist think errors and adverse outcomes are the same thing. However, an error refers to the process in which something has gone wrong, a substandard performance, regardless of the outcome. It has been explained by others that such a judgement may have a degree of subjectivity.[2] An adverse outcome refers to the outcome which is unwanted but does not necessarily imply that an error has been made. This is why the term ''adverse outcomes'' is used rather than the term ''complications'', since the latter term is often confused with an error being made. The registration of medical complications that Gebhardt refers to is a registration of surgical adverse outcomes guided by an unambiguous definition of the term ''adverse outcome'', of which only a small percentage is related to errors.[3] Furthermore, some errors will be missed in this registration—that is, errors which have not led to adverse outcomes.

Secondly, with respect to confidentiality, this is relevant in particular for the initial years of such a registry during which it is thoroughly tested and accuracy of the registration may vary widely between participants. Nothing is gained by false positive signals with respect to the high incidence of adverse outcomes in some hospitals, except perhaps by flashing headlines in newspapers. In this respect one may compare the development of such a national registry to the development of a new drug, in which case no one argues about confidentiality and thorough testing until proved safe. Moreover, a pharmaceutical company will probably be sued if it markets a new drug without proper research. It is intended that after this initial period, national adverse outcome data will become available to the public with respect to probability of an adverse outcome given certain types of surgery.